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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,527	12/27/2001	Raymond L. Houghton	210121.513C1	7914

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EXAMINER	
WILDER, CYNTHIA B	

ART UNIT	PAPER NUMBER
1637	

MAIL DATE	DELIVERY MODE
12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/033,527	**Applicant(s)** HOUGHTON ET AL.	
	Examiner Cynthia B. Wilder, Ph.D.	**Art Unit** 1637	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 December 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *37,40,41 and 44-46*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment to advisory action.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Cynthia B. Wilder, Ph.D.
Patent Examiner
Art Unit: 1637

Attachment to Advisory Action

1. Applicant's amendment filed on 12/4/2006 is acknowledged and will be entered. All of the arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons that follow.

Applicant's Traversal and Examiner's Response

Issue: Claims 37, 40-41 and 44-46 are rejected under 35 USC 112 first paragraph as lacking enablement.

2. In response to Applicant's arguments that the specification clearly describes that the recited sequences of SEQ ID NOS: 7 and 75 are overexpressed in breast tumor tissues as compared to normal breast, the Examiner respectfully disagrees because the specification does not make any specific reference to SEQ ID NOS: 7 and 75 as indicative of overexpression in breast tumor tissue. The only fact Applicant has asserted with respect to SEQ ID NOS: 7 and 75 is that these sequences are associated with the B305D isoforms A and C and GABAπ (see page 40 of the specification). No further explanation is provided in the specification regarding SEQ ID NOS: 7 and 75. Likewise, Applicant's cited support at page 41 does not provide any direct evidence to support the instant invention as claimed. The cited support merely states that microarray analysis reveals "several candidates were chosen on the basis of favorable tissue specificity profile, including B305D, B311D, B726P, B511S and B522S indicating their overpexpression profiles in breast tumors and/or normal breast versus other normal tissues". No direct reference is made to the actual sequences that are claimed to be indicative of overexpression, such as e.g., SEQ ID NO: 7 or 75. Likewise no statistical data or p-values are provided. Applicant merely identifies the gene by name and does not identify which isoform of the

gene or sequences associated therewith is indicative of an overexpression of breast tumor. Additionally, the level of expression of SEQ ID NO: 7 and 75 in cancer cells versus normal cells is not provided. No comparative levels of expression of SEQ ID NOS: 7 and 75 in cancerous cells versus normal cells as being indicative of tumorogenesis is given.

3. In response to Applicant's arguments that the recited sequences of SEQ ID NOS: 7 and 75 are clearly demonstrated in Figure 7 as being at least two-fold higher in breast tumor tissues as compared to normal breast tissues and are not expressed in the majority of other normal tissues, it is noted that the SEQ ID NOS: 7 and 75 are not referenced in the Figure 7, rather the Figure 7 demonstrates mRNA expression levels for "lipophillinB + GABA + B305D + B726P". There is no indication from the Figure 7 that the expression levels of mRNA are indicative of overexpression of breast tumor tissues based on the presence of SEQ ID NOS: 7 and 75.

4. In response to Applicant's arguments that the page 48 provides additional support that the expression of B305D is highly overexpressed in numerous breast tumor tissue types; while the Examiner agrees that the page 48 of the specification states that the B305D gene is highly overexpressed in various types of breast tumor tissues, the examiner maintains that no direct reference is made to either SEQ ID NO: 7 or 75 as claimed. Likewise, to reiterate the specification teaches that SEQ ID NOS: 1, 3 and 5-7 are associated with the B305D isoforms and the SEQ ID NOS: 73-75 are associated with GABA. Therefore, the relevance of SEQ ID NOS: 7 and 75 and the cited support is not clear because B305D is not limited to SEQ ID NO: 7 or 75. These sequences are also not limited to the expression level of "lipophillinB + GABA + B305D

+ B726P" as demonstrated in the Figure 7. While the Examiner further acknowledges Applicant's citation of literature demonstrating tumor overexpression in tissues as being indicative of a diagnosis of a disease, it is noted that Applicant's specification does not support the claims as currently written. As noted in the prior Office action, there is no evidence of record or suggested in the art that the utilization of the SEQ ID NO: 7 and 75 would be helpful in the diagnosis of cancers or breast cancers. Many proteins are highly expressed in normal tissues and diseases tissues. Therefore, one needs to know, e.g., that the claimed polynucleotides are either present only in cancer tissue to the exclusion of normal tissues or is expressed in significantly higher levels in diseased tissues compared to normal tissues (overexpression). Applicant's arguments are not sufficient to overcome the rejection under 35 USC 112 first paragraph.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cbw

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

12/26/06